

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

NADEZDA STEELE-WARRICK,

individually and on behalf of all others similarly
situated,

Plaintiff,

-against-

MICROGENICS CORPORATION and THERMO
FISHER SCIENTIFIC, INC.,

Defendants.

No. 19 Civ. 06558 (VMS)

**MEMORANDUM OF LAW IN OPPOSITION TO
DEFENDANT MICROGENICS'S MOTION TO DISMISS AND MOTION TO STRIKE**

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TABLE OF CONTENTS

PAGE NO.

TABLE OF AUTHORITIES	iv-vii
PRELIMINARY STATEMENT	1
FACTUAL BACKGROUND.....	2
I. DOCCS CONTRACTS WITH DEFENDANTS FOR DRUG TESTING SERVICES.....	2
A. Defendants Supplied DOCCS with the Indiko Plus Testing System Knowing It Would Be Used to Discipline Incarcerated Persons	2
B. Defendants’ Ongoing Maintenance, Training, and Support Services.....	3
C. Defendants’ Testimony at Disciplinary Hearings.....	3
II. DEFENDANTS’ TESTING RESULTS WERE MANIFESTLY UNRELIABLE, CAUSING THOUSANDS OF PEOPLE TO SUFFER FORESEEABLE HARM.....	4
A. Defendants’ Testing Services Had Significant “Cross-Reactivity” Failures.....	4
B. As a Direct Result of Defendants’ Insistence on the Accuracy and Reliability of Their Tests, Thousands of People Were Punished	4
C. DOCCS Terminated the Contract and Reversed The Findings of Disciplinary Decisions Because of the Unreliability of Defendants’ Testing Services	6
PROCEDURAL BACKGROUND.....	6
ARGUMENT	7
I. PLAINTIFF’S NEGLIGENCE CLAIM IS SUFFICIENT.....	7
A. Defendants Owed Plaintiff a Duty to Exercise Reasonable Care in Providing Testing Services at DOCCS Facilities	8
1. Like the Laboratory in <i>Landon</i> , Defendants Were “Best Positioned” to Prevent False Positive Results	10
2. Defendants Violated Applicable Testing Standards	11
3. There Is No Basis to Limit <i>Landon</i> ’s Holding.....	13

B.	Plaintiff Has Sufficiently Alleged That Defendants Breached This Duty.....	17
II.	PLAINTIFF’S CLASS ALLEGATIONS SHOULD NOT BE STRICKEN.....	19
A.	Defendants’ Attempt to Litigate Class Certification Is Premature	20
B.	Every Member of the Putative Class Was Injured by Defendants’ Negligence	22
C.	This Is Not a Mass Tort Personal Injury Case	23
	CONCLUSION.....	25

TABLE OF AUTHORITIES

PAGE NO.

Cases

<i>Amchem Prods. Inc. v. Windsor</i> , 521 U.S. 591 (1997).....	24
<i>Amig v. Cty. of Juniata</i> , 2020 WL 102998 (M.D. Pa. Jan. 8, 2020).....	11, 17
<i>Ashcroft v. Iqbal</i> , 556 U.S. 662 (2009).....	7
<i>Bell Atl. Corp. v. Twombly</i> , 550 U.S. 544 (2007).....	7
<i>Berry v. Nat’l Med. Servs., Inc.</i> , 292 Kan. 917, 922, 257 P.3d 287 (2011).....	17
<i>Blagman v. Apple Inc.</i> , 2013 WL 2181709 (S.D.N.Y. May 20, 2013)	22
<i>Braverman v. Bendiner Schlesinger, Inc.</i> , 121 A.D.3d 353 (2d Dep’t 2014).....	13, 16, 17
<i>Chapman v. Labone</i> , 460 F. Supp. 2d 989 (S.D. Iowa 2006)	17
<i>Chen-Oster v. Goldman, Sachs & Co.</i> , 877 F. Supp. 2d 113 (S.D.N.Y. 2012).....	21
<i>Coleman v. Town of Hempstead</i> , 30 F. Supp. 2d 356 (E.D.N.Y. 1999)	14
<i>Coyle v. United States</i> , 954 F.3d 146 (2d Cir. 2020).....	7
<i>Davito v. AmTrust Bank</i> , 743 F. Supp. 2d 114 (E.D.N.Y. 2010)	21
<i>Drake v. Lab. Corp. of Am. Holdings</i> , 2007 WL 776818 (E.D.N.Y. Mar. 13, 2007).....	14
<i>Duncan v. Afton, Inc.</i> , 991 P.2d 739 (Wyo. 1999).....	17
<i>Elliott v. Lab. Specialists, Inc.</i> , 588 So. 2d 175 (La. Ct. App. 1991).....	17

<i>Espinal v. Melville Snow Contractors, Inc.</i> , 98 N.Y.2d 136 (2002)	14
<i>Farash v. Cont'l Airlines, Inc.</i> , 337 F. App'x 7 (2d Cir. 2009)	19
<i>Flores v. S. Peru Copper Corp.</i> , 414 F.3d 233 (2d Cir. 2003).....	7
<i>Gonzalez v. Caballero</i> , 572 F. Supp. 2d 463 (S.D.N.Y. 2008).....	18
<i>Hamilton v. Beretta U.S.A. Corp.</i> , 96 N.Y.2d 222 (2001)	15
<i>In re Initial Publ. Offering Sec. Litig.</i> , 2008 WL 2050781 (S.D.N.Y. May 13, 2008)	21, 22
<i>In re LIBOR-Based Fin. Instruments Antitrust Litig.</i> , 962 F. Supp. 2d 606 (S.D.N.Y. 2013).....	7, 19
<i>In re Methyl Tertiary Butyl Ether (MBTE) Prods. Liab. Litig.</i> , 241 F.R.D. 435 (S.D.N.Y. 2007)	24
<i>In re Nassau Cnty. Strip Search Cases</i> , 461 F.3d 219 (2d Cir. 2006).....	25
<i>Kassman v. KPMG LLP</i> , 925 F. Supp. 2d 453 (S.D.N.Y. 2013).....	21
<i>Landon v. Kroll Lab. Specialists, Inc.</i> , 22 N.Y.3d 1 (2013)	<i>passim</i>
<i>Lombard v. Booz-Allen & Hamilton, Inc.</i> , 280 F.3d 209 (2d Cir. 2002).....	8, 17, 18
<i>Lynch v. City of New York</i> , 952 F. 3d 67 (2d Cir. 2020).....	7
<i>Nakahata v. N.Y.-Presbyterian Healthcare Sys., Inc.</i> , 723 F.3d 192 (2d Cir. 2013).....	7
<i>Nazarian v. Compagnie Nationale Air France</i> , 989 F. Supp. 504 (S.D.N.Y. 1998).....	18
<i>Palka v. Servicemaster Mgmt. Serv. Corp.</i> , 83 N.Y.2d 579 (1994)	8, 14, 17

<i>Palsgraf v. Long Island R.R. Co.</i> , 248 N.Y. 339 (1928)	14
<i>Pasternack v. Lab. Corp. of Am. Holdings</i> , 27 N.Y.3d 817 (2016)	13, 15, 16
<i>Patterson v. State</i> , 54 A.D.2d 147 (1976)	19
<i>Pawaroo v. Countrywide Bank</i> , 2010 WL 1048822 (E.D.N.Y. Mar. 18, 2010)	19
<i>Quisenberry v. Compass Vision, Inc.</i> , 618 F. Supp. 2d 1223 (S.D. Cal. 2007)	17
<i>Rahman v. Smith & Wollensky Rest. Grp., Inc.</i> , 2008 WL 161230 (S.D.N.Y. Jan. 16, 2008)	21, 22
<i>Roberts v. Los Alamos Nat’l Sec., LLC</i> , 278 F. Supp. 3d 651 (W.D.N.Y. 2017)	18
<i>Sharpe v. St. Luke’s Hosp.</i> , 573 Pa. 90, 96, 821 A.2d 1215 (2003)	17
<i>Shaw v. Psychemedics Corp.</i> , 426 S.C. 194, 200, 826 S.E.2d 281 (2019)	17
<i>Solomon by Solomon v. City of New York</i> , 66 N.Y.2d 1026 (1985)	7
<i>Stagl v. Delta Airlines, Inc.</i> , 52 F.3d 463 (2d Cir. 1995)	7
<i>Stanford v. Kuwait Airways Corp.</i> , 89 F.3d 117 (2d Cir. 1996)	14
<i>State of New York v. Microgenics Corporation et al</i> , No. 902691-20 (2020)	3
<i>Stinson v. Physicians Immediate Care, Ltd.</i> , 269 Ill. App. 3d 659, 664, 646 N.E.2d 930 (1995)	17
<i>Wal-Mart Stores, Inc. v. Dukes</i> , 564 U.S. 338 (2011)	20
<i>Williams v. Utica Coll. of Syracuse Univ.</i> , 453 F.3d 112 (2d Cir. 2006)	18

Statutes

42 U.S.C. § 1983.....	11, 17
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Plaintiff submits this memorandum of law in opposition to Defendant Microgenics's motion to dismiss Plaintiff's First Amended Complaint ("Complaint" or "Compl.") and to strike Plaintiff's Class Allegation.¹

PRELIMINARY STATEMENT

Defendants Microgenics and Thermo Fisher Scientific ("Defendants") are subject to liability under the single claim alleged in the Complaint: negligence. Seeking to hold Plaintiff to a pleading standard far above what Federal Rule of Civil Procedure 8 requires, Defendants submitted a motion to dismiss the claim that they *wish* Plaintiff alleged: strict products liability. But the only question for this Court is whether Plaintiff has sufficiently pleaded the four elements required to assert a claim for negligence under New York law: duty, breach, causation, and injury. The easy answer to that question is yes.

First, the New York Court of Appeals has held that drug testing corporations like Defendants owe a duty to individual test subjects in the criminal justice context. *Landon v. Kroll Lab. Specialists, Inc.*, 22 N.Y.3d 1, 6-7 (2013). *Landon* controls, is squarely on point, and fully supports the nature and sufficiency of Plaintiff's claim.

Second, breach is a jury question not appropriate for a motion to dismiss, and, nevertheless, Plaintiff more than adequately alleges that Defendants breached their duty to her, and others similarly situated to her, by negligently providing a testing system and related services to the New York Department of Corrections and Community Supervision ("DOCCS") that was so extraordinarily unreliable and inaccurate that DOCCS reversed and expunged the disciplinary decisions and concomitant penalties of thousands of incarcerated persons. The

¹ Plaintiff notes that Defendant Thermo Fisher Scientific joins Defendant Microgenics's motion. *See* Defendant Thermo Fisher Scientific's Memorandum of Law in Support of its Motion to Dismiss, at 1.

Complaint’s detailed allegations about the nature of this negligence—for example, that Defendants negligently testified at disciplinary hearings that their preliminary screening tests could be relied upon to impose disciplinary sanctions, when in fact such use was contrary to Defendants’ own standards, and Defendants already knew that their testing system had significant cross-reactivity issues—are more than sufficient to plead a breach under New York law.

Third, Microgenics does not contest causation or injury – nor could it.

Defendants’ acts directly caused thousands of incarcerated persons to endure significant harms and damages: months of solitary confinement, delayed release from incarceration, and denial of privileges like family visitation, packages, and mail, to name a few. They are liable to Plaintiff and putative class members for these harms.

Microgenics’s motion to strike is equally unmeritorious. It is simply a premature opposition to class certification in disguise, and it fails both procedurally and on its merits.

This Court should deny Microgenics’s motion in its entirety.

FACTUAL BACKGROUND

I. DOCCS CONTRACTS WITH DEFENDANTS FOR DRUG TESTING SERVICES

A. Defendants Supplied DOCCS with the Indiko Plus Testing System Knowing It Would Be Used to Discipline Incarcerated Persons

In May 2018, DOCCS issued an invitation for bids, seeking “reagent rentals of bench top urinalysis analyzer services to be used in its 52 correctional facilities for inmates.” Compl. ¶ 13. DOCCS sought to identify incarcerated persons who used illegal drugs so they could be charged and disciplined. *Id.* ¶ 40.

Defendants submitted a bid and, in September 2018, DOCCS and Defendants entered into a five-year contract, #CC161458 (the “Contract”), to supply testing using Indiko

Plus urinalysis analyzers (“Indiko Plus”), a system developed by Thermo Fisher and marketed to conduct urinalysis drug testing. *Id.* ¶¶ 22-23. The Contract required that Defendants warrant and represent that the products delivered would conform to the manufacturer’s specifications, performance standards, and documentation. *Id.* ¶ 30. Defendants specifically warranted to DOCCS that their system would “add clarity” to the screening process and had “no significant cross-reactivity” issues. *State of New York v. Microgenics Corporation et al*, No. 902691-20 (2020), N.Y. St. Cts. Elec. Filing [NYSCEF] Doc. No. 1, Complaint (“DOCCS Complaint”), ¶ 19.

Defendants knew that DOCCS would charge and severely discipline people who tested positive on the Indiko Plus system, with no confirmatory testing to verify the results. Compl. ¶ 40. Defendants’ own standards for the Indiko Plus system state that the system should only be used as an initial screen, and confirmatory testing is required to verify any positive result. *Id.* ¶ 34. Yet Defendants marketed and then contracted to provide this testing system to DOCCS, knowing it would not be used in conjunction with confirmatory testing. *Id.* ¶ 35.

B. Defendants’ Ongoing Maintenance, Training, and Support Services

Under the terms of the Contract, Defendants were obligated to provide the Indiko Plus benchtop machine to each correctional facility, as well as provide all testing chemicals, conduct all maintenance, provide helpdesk support, and train all master trainers at DOCCS facilities. *Id.* ¶¶ 22, 26-29. Defendants were thus contracting to be part of the everyday operation of this testing system and did in fact remain involved on a day-to-day basis. *Id.* ¶¶ 26, 27, 30, 38.

C. Defendants’ Testimony at Disciplinary Hearings

Defendants contracted to testify at disciplinary hearings of incarcerated persons charged with misconduct on the basis of positive test results from Defendants’ drug testing

system. *Id.* ¶ 28. Defendants knew that their testing system was not designed to provide test results that would be sufficiently reliable to discipline incarcerated persons. *Id.* ¶ 34. Yet, Defendants repeatedly testified as to the reliability of these tests in hearings where, as a result of such testimony, incarcerated persons were disciplined. *Id.* ¶ 29.

II. DEFENDANTS' TESTING RESULTS WERE MANIFESTLY UNRELIABLE, CAUSING THOUSANDS OF PEOPLE TO SUFFER FORESEEABLE HARM

A. Defendants' Testing Services Had Significant "Cross-Reactivity" Failures

In short order, Defendants' testing system began to identify and charge incarcerated persons as having used illegal drugs without a reliable basis for doing so. *Id.* ¶ 43. As a result of "cross-reactivity" issues, the Indiko Plus testing system led to thousands of incarcerated persons being unreasonably and unjustifiably accused of having used illegal and controlled substances. *Id.* Many incarcerated persons had complained of inaccurate test results, and DOCCS employees had also raised concerns. *Id.* ¶¶ 90-92. Defendants knew of these widespread concerns, objections, and systemic errors. *Id.* ¶ 45.

Defendants warranted that their testing system was accurate and reliable and DOCCS relied on the Indiko Plus to discipline incarcerated persons. *Id.* ¶¶ 29-30. Defendants testified to the reliability of their testing system at disciplinary hearings, despite knowing that the system could not produce reliable test results and that it, further, suffered serious cross-reactivity issues. *Id.* ¶¶ 29, 38, 43. By testifying, Defendants supported and endorsed DOCCS's continued use of this system to discipline incarcerated persons. *Id.* ¶ 40.

B. As a Direct Result of Defendants' Insistence on the Accuracy and Reliability of Their Tests, Thousands of People Were Punished

The disciplinary infractions imposed upon the putative class members based upon unreliable Indiko Plus test results included, but were not limited to, weeks or months of restrictive and punitive confinement and the loss of various privileges. *Id.* ¶ 52. As a direct

consequence of these unreliable test results and Defendants' testimony supporting their claimed reliability, some incarcerated persons were held in prison for months beyond their release dates. *Id.* ¶ 52. Even those who had obtained benefits and additional privileges through accomplishments and limited disciplinary incidents and dispositions were not left unscathed. Many lost preferred work and housing assignments, were denied participation in the Family Reunion Program, were removed from education and treatment programs, or were transferred from preferred facilities. *Id.* ¶ 52.

Ms. Nadezda Steele-Warrick's experience exemplifies the harm caused by unreliable test results from the Indiko Plus testing system. Ms. Steele-Warrick tested positive for Suboxone/buprenorphine on April 14, 2019. *Id.* ¶¶ 60-64. She was charged and immediately taken from her coveted and earned private room, handcuffed, and placed into a disciplinary confinement, keeplock cell for 11 days. *Id.* ¶ 67. She lost access to her personal property and her ability to interact with others, particularly her family. *Id.* ¶¶ 68-74. She was traumatized by being humiliated in this way. *Id.* ¶ 74.

Ms. Steele-Warrick was brought to a disciplinary hearing while still in keeplock. *Id.* ¶ 76. She testified that she did not ingest or use any illegal substances. *Id.* ¶ 77. The DOCCS hearing officer found Ms. Steele-Warrick guilty on the basis of the test result from Defendants' testing system. *Id.* ¶ 78. As a result of the guilty disposition and denial of her due process rights, Ms. Steele-Warrick lost a host of privileges and rights, including the Family Reunion Program, a program where she had the opportunity to spend significant personal time with her husband and child. *Id.* ¶¶ 80-86. She was eventually released from DOCCS custody, but remained terrified that this erroneous drug-related disciplinary disposition would adversely affect or interfere with

her pending immigration proceedings. *Id.* ¶ 85. The strain of her ordeal caused lasting harm to Ms. Steele-Warrick. *Id.* ¶ 86.

C. DOCCS Terminated the Contract and Reversed The Findings of Disciplinary Decisions Because of the Unreliability of Defendants’ Testing Services

Ultimately, after an unprecedented number of questionable positive results cast doubt on the reliability of test results from the Indiko Plus system, DOCCS reversed all disciplinary determinations based on such testing for Suboxone/buprenorphine, AB Pinaca, opiates, and THC. *Id.* ¶ 46. Contrary to Defendants’ representations in the Contract that their services would be error free, DOCCS’s wholesale reversal of disciplinary dispositions based upon the Indiko Plus test results indicate that Defendants failed to reasonably ensure that their machines and assays functioned properly, resulting in thousands of unreliable test results for suboxone/buprenorphine, AB Pinaca, opiates, and THC. *Id.* ¶ 43.

After an internal investigation of the circumstances surrounding the unreliable test results obtained through the Indiko Plus system, DOCCS terminated the Contract for cause. *Id.* ¶ 48. DOCCS then sued Defendants in New York State Supreme Court, alleging that Defendants’ equipment, products, procedures, and services were inadequate, failed to operate according to their intended uses, and, as a result, produced unreliable positive test results. *Id.* ¶ 50. The New York State Inspector General is also investigating this matter. *Id.* ¶ 49.

PROCEDURAL BACKGROUND

Plaintiff filed her original class action complaint in November 2019 and amended it as of right on March 5, 2020. Defendants served motions to dismiss the original complaint and renewed their motions to dismiss the First Amended Complaint on April 24, 2020.

ARGUMENT

In deciding a motion to dismiss for failure to state a claim, the Court must “accept well pleaded factual assertions as true” and “draw all reasonable factual inferences in favor of the plaintiff.” *Lynch v. City of New York*, 952 F. 3d 67, 76 (2d Cir. 2020). A complaint need only “contain sufficient factual matter, accepted as true, to ‘state a claim to relief that is plausible on its face.’” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). “To be plausible, the complaint need not show a probability of plaintiff’s success,” but need only “evidence more than a mere possibility of a right to relief.” *Nakahata v. N.Y.-Presbyterian Healthcare Sys., Inc.*, 723 F.3d 192, 197 (2d Cir. 2013). In other words, “[a] complaint should not be dismissed for failure to state a claim unless it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief.” *Flores v. S. Peru Copper Corp.*, 414 F.3d 233, 242 (2d Cir. 2003) (quotation marks omitted). And dismissal at the pleadings stage is particularly inappropriate where the facts are peculiarly within the possession and control of the defendant. *In re LIBOR-Based Fin. Instruments Antitrust Litig.*, 962 F. Supp. 2d 606, 617 (S.D.N.Y. 2013). Plaintiff has alleged more than sufficient well-pleaded facts to sustain her Complaint. Defendants’ motions should be denied.

I. PLAINTIFF’S NEGLIGENCE CLAIM IS SUFFICIENT

“In order to establish a *prima facie* case of negligence under New York law, a claimant must show that: (1) the defendant owed the plaintiff a cognizable duty of care; (2) the defendant breached that duty; and (3) the plaintiff suffered damage as a proximate result of that breach.” *Stagl v. Delta Airlines, Inc.*, 52 F.3d 463, 467 (2d Cir. 1995) (citing *Solomon by Solomon v. City of New York*, 66 N.Y.2d 1026, 1027 (1985)); accord *Coyle v. United States*, 954 F.3d 146, 148 (2d Cir. 2020). The New York Court of Appeals has squarely held that corporations like Defendants who are testing providers in criminal justice contexts “ha[ve] a duty

to the test subject to perform [their] drug test in keeping with relevant professional standards.”

Landon v. Kroll Lab. Specialists, Inc., 22 N.Y.3d 1, 6-7 (2013).²

Faced with this binding authority, Microgenics attempts to minimize Defendants’ role in the drug testing regimen and related prison disciplinary process. It also argues that Plaintiff has failed to allege any breach, but it has no answer to Plaintiff’s well-pleaded allegations that Defendants knew or should have known of significant issues with their testing services. Yet Defendants continued to provide those services, including by attesting to their purported reliability and efficacy at disciplinary hearings. These allegations are more than adequate at the pleadings stage.

A. Defendants Owed Plaintiff a Duty to Exercise Reasonable Care in Providing Testing Services at DOCCS Facilities

Plaintiff alleged that, “[a]s the entities responsible for providing drug testing services in DOCCS’s facilities (including machines, assays, services, training, installation, and maintenance), Defendants owed incarcerated persons in those facilities a duty to abide by applicable drug testing standards and to ensure that the testing was accurate and reliable.” Compl. ¶ 33. “Defendants knew that positive drug screen results from the Indiko Plus urinalysis analyzers would be used to discipline persons in DOCCS’s custody – without verification by any other means – and they did nothing to stop such discipline from being imposed,” *id.* ¶ 40, even though they “were also negligent in failing to ensure that the Indiko Plus urinalysis analyzers produced accurate preliminary drug test screens,” *id.* ¶ 42, including in the context of “cross-reactivity issues,” *id.* ¶ 43. Despite significant concerns regarding the reliability of the testing

² Microgenics has not challenged the sufficiency of Plaintiff’s causation and damages allegations. Under New York law, breach and proximate cause are questions for the finder of fact, *Palka v. Servicemaster Mgmt. Serv. Corp.*, 83 N.Y.2d 579, 585 (1994), and are not properly decided at the pleading stage, *Lombard v. Booz-Allen & Hamilton, Inc.*, 280 F.3d 209, 215-16 (2d Cir. 2002).

regimen, “Defendants continued to testify at disciplinary hearings that their test results were reliable.” *Id.* ¶ 45. “The natural and foreseeable consequence of Defendants’ negligent failure to ensure that its products and services complied with applicable standards and produced accurate results was that thousands of incarcerated persons were punished for false and unreliable positive drug tests.” *Id.* ¶ 51.

In *Landon v. Kroll*, the New York Court of Appeals held that drug testing providers owe their test subjects a duty of care, including a duty to supply a testing system that is “in keeping with relevant professional standards.” N.Y.3d at 6-7. While serving a term of probation, the plaintiff, Eric Landon, was required to submit to a drug test. *Id.* The test was administered by Kroll Laboratory Specialists, Inc., a company that had contracted with the probation department to supply testing services. *Id.* at 4. Kroll reported that Landon was positive for cannabinoids. *Id.* Landon’s probation was extended as a result of this report. *Id.* Landon sued Kroll, claiming in part that Kroll had supplied a service that used low cutoff levels and produced unreliable results. *Id.* at 4-5. The Court of Appeals held that Kroll owed Landon a duty of reasonable care with respect to these alleged acts and omissions. *Id.* at 6-7.

Landon controls. Defendants here, like Kroll in *Landon*, contracted with a criminal justice agency to provide drug testing services. Compl. ¶ 26. Defendants, like Kroll, knew that their services would be used to impose harsh discipline, including extended imprisonment and solitary confinement. *Id.* ¶ 40. Defendants knew that they were the sole testing provider. *Id.* Plaintiff, like Eric Landon, did not have a choice about whether or not she was tested. Here however, unlike in *Landon*, Defendants further knew that they were contractually required to testify regularly at disciplinary hearings, and did so by inaccurately and falsely confirming the testing system’s accuracy and reliability as it was being used and relied upon by

DOCCS. *Id.* ¶¶ 45, 52. Defendants, under *Landon*, owed a duty of care to Plaintiff, and those similarly situated, to provide testing services and results that were sufficiently reliable to discipline incarcerated persons under DOCCS testing standards.

Microgenics seeks to limit *Landon*, by arguing: (1) that Defendants are differently situated from Kroll Labs such that *Landon* does not control; (2) that Plaintiff has failed to satisfy *Landon*'s pleading standards; and (3) that *Landon* is limited to its facts as a matter of law by subsequent precedent. Microgenics is wrong on all counts.

1. Like the Laboratory in *Landon*, Defendants Were “Best Positioned” to Prevent False Positive Results

Microgenics contends that it is merely a “contractor that supplies products and equipment for in-house urinalysis drug screens,” Memorandum of Law in Support of Defendant Microgenics's Motions to Dismiss and Strike (“Micro. Br.”), at 12, that it “did not provide laboratory drug-test services to DOCCS” but rather “supplied drug-screening equipment and training on how to use the equipment,” *id.* at 11, and that “[t]hat distinction is dispositive under *Landon*,” *id.* at 12. Microgenics is being, at best, disingenuous.

Defendants not only provided the Indiko Plus benchtop machine to each prison, they also supplied *all* of the testing chemicals, carried out *all* master training, did *all* maintenance, and remained in constant contact with DOCCS regarding the testing system. Compl. ¶¶ 22, 26-29. Defendants' key and constant role in the testing system is evident from the fact that Defendants testified at disciplinary hearings about the nature of testing, the reliability of tests, and the reliability of incarcerated persons' positive test results.³ *Id.* ¶¶ 29, 40, 45. This role

³ Although unnecessary to resolve the present motion before the Court, Plaintiff notes that the limited document production she has received so far demonstrates that Defendants participated in the testing program even more closely than this; when DOCCS raised concerns about false positives early on, Defendants sent technicians to the facilities to evaluate how tests were being carried out. Those employees confirmed for DOCCS that all testing was

in testifying makes sense in light of what Defendants had contracted to provide DOCCS: a comprehensive testing solution that DOCCS personnel could operate with no additional expertise, that produced results that were on their face sufficient to trigger discipline for incarcerated persons. *See* DOCCS Complaint ¶¶ 16-21.⁴ Defendants were, as with Kroll Labs in *Landon*, “in the best position to prevent false positive results.” 999 N.E.2d at 679. Defendants are thus subject to the duty at issue in *Landon*.

2. Defendants Violated Applicable Testing Standards

Microgenics further argues that, since Plaintiff “has not plausibly alleged a relevant professional standard governing Microgenics’s contractual obligations to DOCCS,” the Complaint “fails to state a claim under *Landon*.” Micro. Br. at 13. Microgenics is wrong.

First, Microgenics engages in sleight of hand by framing the issue as whether Plaintiff has “plausibly alleged a relevant professional standard ***governing Microgenics’ contractual obligations to DOCCS***.” *Id.* at 13 (emphasis added). That is not the test. The relevant professional standards in *Landon* were not alleged to be incorporated into the contractual relationship between the probation department and Kroll. Rather, the standards were federal standards and the standards recommended by the manufacturer of the oral sample collection device. *Landon*, 22 N.Y.3d at 4. The laboratory in *Landon* had in fact complied with the standards incorporated in its contract with the probation department. *Id.* at 9 (“Kroll

being carried out per Defendants’ testing protocols and that the test results were accurate. Plaintiff will no doubt supplement her complaint in the future with these and other facts that are revealed during discovery.

⁴ In fact, the Middle District of Pennsylvania in January of this year found that an individual incarcerated in a Pennsylvania prison had sufficiently pleaded a 42 U.S.C. § 1983 claim against a private testing company whose sole involvement in the plaintiff’s discipline was that it sold “drug testing kits” that were administered by prison officials. *Amig v. Cty. of Juniata*, 2020 WL 102998, at *4 (M.D. Pa. Jan. 8, 2020). The test maker at issue in *Amig* had a far more attenuated connection to the harm caused to the plaintiff there than the connection between Defendants’ conduct and Plaintiff’s harm here, yet the *Amig* court had no trouble finding the plaintiff’s allegations sufficiently pleaded an Eighth Amendment claim against the private drug company as the state had “delegate[d] the duty to monitor drug use” to it. *Id.*

determined that the sample it received contained cannabinoids in an amount exceeding its 1 ng/mL screen test cutoff level *as provided by its contract* and reported these results to the Probation Department.”) (emphasis added) (Pigott, J., dissenting). Thus, there is no basis for limiting the relevant standard, as Microgenics proposes, to one that only governs contractual relationships.

Second, Plaintiff has, in fact, alleged violations of relevant standards in her Complaint. Defendants contracted with DOCCS to provide products that would be “substantially uninterrupted or error-free in operation” and warranted that they would “conform to the manufacturer’s specifications, performance standards, and documentation.” Compl. ¶ 30. Defendants knew that DOCCS would use their services to discipline incarcerated persons without further testing. *Id.* ¶ 35. Defendants’ own standards for the use of these products and services—or “descriptions,” as Microgenics describes them, Micro. Br. at 13—stated that such testing services should not be relied upon without confirmatory testing, Compl. ¶ 34. Then, Defendants testified at DOCCS disciplinary hearings “that the results from the Indiko Plus urinalysis analyzers could be relied on as a basis for disciplining incarcerated persons, even though Defendants knew that the results were only preliminary screens.” *Id.* ¶ 38.

And, not only did Defendants provide testing services that they knew would be unreliable indicators to discipline incarcerated persons, and then testified to the contrary, their tests most likely failed to even work as preliminary screens. *Id.* ¶ 42. Defendants specifically warranted to DOCCS that their system would “add clarity” to screening and had “no significant cross reactivity” issues. *See* DOCCS Complaint, ¶ 19. The tests—which were used to check if an incarcerated person had consumed illegal drugs—confused these drugs with legal substances thousands of times. *Id.* ¶ 43.

Microgenics makes much of the fact that DOCCS has used preliminary screens for disciplining incarcerated persons for many years. Micro. Br. at 15. Yet, in all that time, Plaintiff knows of only *one instance*—this instance—in which DOCCS has cancelled a contract for testing services and overturned all positives because the testing system was so unreliable. *Id.* ¶¶ 46-48. In other words, Defendants provided testing services that not only failed their *own* standard operating requirements, a fact that Defendants did not disclose in testifying at DOCCS hearings, but Defendants’ services failed *DOCCS’s* standards so egregiously that the agency reversed every disciplinary decision premised on Defendants’ tests. DOCCS subsequently sued Defendants on these grounds. DOCCS Complaint, ¶ 28 (“The equipment, products, procedures and services provided by the Defendants to DOCCS under the Contract were inadequate and deficient, failed to operate according to their intended use, and resulted in numerous false positive test results with respect to various drugs, including the opioid Buprenorphine, Synthetic Cannabinoids, Cannabinoids, and Opiates.”). That is all Plaintiff need plead at this stage in the litigation. She has satisfied *Landon’s* dictates.

3. There Is No Basis to Limit *Landon’s* Holding

As an alternative, Microgenics argues that *Landon’s* holding is “limited” and that subsequent caselaw has undermined that judgment. Micro. Br. at 11 (citing *Pasternack v. Lab. Corp. of Am. Holdings*, 27 N.Y.3d 817 (2016)); *id.* at 13 (citing *Braverman v. Bendiner Schlesinger, Inc.*, 121 A.D.3d 353, 359 (2d Dep’t 2014)). Decisions from courts in New York and around the country have, contrary to Microgenics’s suggestion, reinforced the existence and appropriateness of the duty Defendants owed to Plaintiff and those similarly situated to her.

The *Landon* court concluded that a testing provider owed a duty of care to a test subject under the “force or instrument of harm” *Espinal* exception because the harm alleged was “not remote or attenuated” given that an unreliable testing system “will have profound,

potentially life-altering, consequences for a test subject,” and the testing provider is in the “best position” to prevent such harm. *Landon*, 22 N.Y.3d at 6 (citing *Espinal v. Melville Snow Contractors, Inc.*, 98 N.Y.2d 136, 140 (2002)). The same reasoning applies here.

New York courts have long held that a defendant may owe a duty of care where its conduct was “not directed to a faceless or unlimited universe of persons,” but rather created a risk for “a known and identifiable group.” *Palka*, 83 N.Y.2d at 589; *see also Stanford v. Kuwait Airways Corp.*, 89 F.3d 117, 125 (2d Cir. 1996) (“[T]he risk reasonably to be perceived defines the duty to be obeyed, and risk imports relation.”) (quoting *Palsgraf v. Long Island R.R. Co.*, 248 N.Y. 339, 344 (1928)). In this case, Defendants’ duties extended to a precise and easily definable class of people: incarcerated persons subject to DOCCS rules of behavior who could be disciplined by DOCCS on the strength of an unreliable testing system provided by Defendants. This is not a “faceless or unlimited universe of persons”; rather, this is a clearly defined and limited class of people who Defendants, in contracting with DOCCS, *knew* would be the very subjects of such testing.

Plaintiff has handily pleaded the severe harm she and others similarly situated suffered as a result of being subject to this unreliable testing. In addition to loss of access to the Family Reunification Program, confinement in keeplock, and other trauma, Plaintiff’s due process rights were also violated. Compl. ¶¶ 69-86. These are all “profound, potentially life-altering, consequences” that flowed directly from Defendants’ actions. *Landon*, 22 N.Y.3d at 6; *see also Coleman v. Town of Hempstead*, 30 F. Supp. 2d 356, 365 (E.D.N.Y. 1999) (“damaging and far-reaching consequences” of false drug test counseled for duty); *Drake v. Lab. Corp. of Am. Holdings*, 2007 WL 776818, at *2 (E.D.N.Y. Mar. 13, 2007), *aff’d*, 417 F. App’x 84 (2d Cir. 2011) (finding analogous duty).

Defendants were without doubt in the “best position” to prevent this harm.

Landon, 22 N.Y.3d at 6; *see also Hamilton v. Beretta U.S.A. Corp.*, 96 N.Y.2d 222, 233 (2001) (a “key” factor favoring recognition of a duty is that “the defendant [is] in the best position to protect against the risk of harm”). They marketed the testing system, installed it, maintained it, and repeatedly and consistently testified to its efficacy. Compl. ¶¶ 22, 26-30. The testing of prisoners was, in most cases, carried out by DOCCS personnel, but they were laypeople who were trained by Defendants. *Id.* ¶ 26. In the end, the entire system was validated and overseen by Defendants, who gave their professional imprimatur to it when they testified in support of it at hearings. *Id.* ¶ 29. The duty to Plaintiff, thus, rests most clearly on Defendants.

Microgenics’s cited cases do not alter or undermine this analysis. In *Pasternack v. Lab. Corp. of Am. Holdings*, 27 N.Y.3d 817 (2016), the New York Court of Appeals found that a drug laboratory did not owe a pilot a duty to inform him of Federal Aviation Authority (FAA) regulations. The FAA and the Department of Transportation mandated that pilots be drug tested randomly and that, once they arrived for testing, they not leave the testing site without following certain procedures. *Id.* at 820. The plaintiff told the technician on duty that he was planning to leave the testing site and, in response, she did not inform him of the relevant FAA regulations. *Id.* at 822. The plaintiff left, the technician marked him as having done so, and the FAA later investigated. *Id.* After the investigation, the FAA revoked the pilot’s license. *Id.* The decision was upheld on appeal but was eventually reversed. *Id.* at 823. Plaintiff sued the company contracted to collect test samples, and the court refused to “[r]ecogniz[e] a duty of care for any violation of federal regulations and guidelines unrelated to the actual performance of scientific testing of the biological sample.” *Id.* at 826.

In so ruling, the court reaffirmed *Landon*'s holding regarding the "duty of care owed by laboratories to ensure accurate testing procedures." *Id.* It clarified that the testing procedure of the biological sample must be at issue for the duty to run to the party providing testing. As noted *supra*, Argument § I.A.2, that is precisely the issue in this case. The Complaint alleges that Defendants violated both their own and DOCCS's standards for providing accurate test results, not that Defendants were violating some "ministerial federal [or here, state] regulations unrelated to the actual performance of scientific testing." *Pasternack*, 27 N.Y.3d at 826.

The same is true of *Braverman v. Bendiner & Schlesinger, Inc.*, 121 A.D.3d 353, 355-56, 990 N.Y.S.2d 605, 607 (2d. Dep't 2014), where the Second Department found that a testing laboratory did not owe a duty to plaintiffs who were required to be tested as part of a drug court-supervised program. The laboratory did clinical drug tests for a wide variety of people, including people who were not subject to court supervision. *Id.* at 355. Plaintiffs did "not take issue with the manner in which the tests were performed or challenge the accuracy of the results reported," and there was no allegation that the laboratory was required to do any other kind of test under its contract with the court. *Id.* At issue was simply "whether the defendants' duty of reasonable care includes the duty to label or place a disclaimer on a report, so as to indicate that the results are to be used only for clinical purposes" where "there are no professional standards implicated." *Id.* at 359. The court held that, in the drug court context, where "[t]he plaintiffs, and others similarly situated, have the benefit of attorneys who are directly responsible for representing their interests in court, and the benefit of the members of the judiciary, who are the gatekeepers directly responsible for protecting the integrity of the court proceedings," there was no "overriding social benefit to be achieved from imposing such a duty." *Id.* at 362.

In this case, of course, unlike in *Braverman*, Plaintiff is alleging a violation of professional standards, including those adopted by Defendants themselves and by DOCCS. Further, and critically, Plaintiff and others like her had no recourse to attorneys, courts, or anyone else to protect them; upon receiving positive test results, they were subject to disciplinary hearings in a context where hearing officers had been told repeatedly by Defendants that the tests were reliable and accurate. There is thus a clear “overriding social benefit to be achieved from imposing” a duty on Defendants here. *Id.* In short, *Landon* controls this issue and Plaintiff has substantiated the duty of care Defendants owed to her and others similarly situated.⁵

B. Plaintiff Has Sufficiently Alleged That Defendants Breached This Duty

Microgenics argues that, notwithstanding any duty it may have owed to Plaintiff and those similarly situated, Plaintiff “has not plausibly alleged that Microgenics breached any such duty” and thus the Complaint should be dismissed at the pleadings stage. Micro. Br. at 13. Microgenics’s argument ignores the allegations in the Complaint and controlling New York law.

Breach is a quintessential jury question. It cannot be resolved at the pleading stage. *See Lombard*, 280 F.3d at 215-16; *Palka*, 83 N.Y.2d at 585. “Once the court has determined the existence of a duty of care, it is then the factfinder’s job to determine whether the

⁵ This or a closely aligned duty has been recognized by the vast majority of courts around the country to have considered the issue. In 2019, in *Shaw v. Psychemedics Corp.*, the South Carolina Supreme Court cited *Landon* to find a duty on drug testing laboratories testing employees of their contractual counterparties. 426 S.C. 194, 200, 826 S.E.2d 281, 284 (2019). The appellate courts of Kansas, Pennsylvania, Wyoming, Illinois, and Louisiana have found the same. *See Berry v. Nat’l Med. Servs., Inc.*, 292 Kan. 917, 922, 257 P.3d 287, 291 (2011) (“A laboratory testing facility owes a duty to those whose specimens it tests to accurately report results and not to mischaracterize or misinterpret those results.”); *Sharpe v. St. Luke’s Hosp.*, 573 Pa. 90, 96, 821 A.2d 1215, 1219 (2003); *Duncan v. Afton, Inc.*, 991 P.2d 739, 745 (Wyo. 1999); *Stinson v. Physicians Immediate Care, Ltd.*, 269 Ill. App. 3d 659, 664, 646 N.E.2d 930, 934 (1995); *Elliott v. Lab. Specialists, Inc.*, 588 So. 2d 175, 176 (La. Ct. App. 1991), writ denied, 592 So. 2d 415 (La. 1992). District Courts in California and Iowa have also identified the same duty. *See Quisenberry v. Compass Vision, Inc.*, 618 F. Supp. 2d 1223, 1230 (S.D. Cal. 2007); *Chapman v. Labone*, 460 F. Supp. 2d 989, 1001 (S.D. Iowa 2006). And, as noted *supra*, n.4, the Middle District of Pennsylvania recently held that a drug testing kit manufacturer was a *de facto* state actor for purposes of 42 U.S.C. § 1983 because, by supplying those kits to a correctional facility, it had assumed traditional state functions and could thereby be held liable for its failures. *Amig v. Cty. of Juniata*, No. 1:19-CV-408, 2020 WL 102998, at *4 (M.D. Pa. Jan. 8, 2020).

duty was breached and, if so, whether the breach was the proximate cause of plaintiff's injury.” *Gonzalez v. Caballero*, 572 F. Supp. 2d 463, 467 (S.D.N.Y. 2008); *accord Nazarian v. Compagnie Nationale Air France*, 989 F. Supp. 504, 510 (S.D.N.Y. 1998) (“At this stage, the Court must determine only if any facts exist that would allow plaintiffs to recover.”); *Roberts v. Los Alamos Nat’l Sec., LLC*, 278 F. Supp. 3d 651, 657 (W.D.N.Y. 2017), *aff’d*, 763 F. App’x 121 (2d Cir. 2019). The Second Circuit has held that a court should not approach such a question even where a plaintiff’s “theory faces serious difficulties with regard both to a lack of reasonable care and causation.” *Lombard*, 280 F.3d at 215; *accord Williams v. Utica Coll. of Syracuse Univ.*, 453 F.3d 112, 119 (2d Cir. 2006).

Plaintiff’s allegations of breach easily meet these standards and are far from “conclusory.” Micro. Br. at 14. Defendants supplied DOCCS with testing equipment that was warranted to be fit for the purpose of disciplining incarcerated persons on the basis of two preliminary screening tests, trained personnel in the use of Defendants’ testing system, supplied all of the chemicals to run the system, monitored DOCCS’s use of the system, and testified repeatedly that this testing system was reliable and fit for its warranted purpose.⁶ Compl. ¶¶ 22, 26-30. Defendants were told of concerns regarding cross-reactivity in their testing system⁷ and yet continued to attest to its efficacy and reliability.⁸ *Id.* ¶ 45. The testing system failed and

⁶ Microgenics’s argument that there is supposedly no breach because DOCCS had a long history of using screening tests, Micro. Br. at 15, is similarly a red herring. DOCCS had contracted with Defendants to supply a testing system that was sufficiently reliable to discipline Plaintiff and others similarly situated. Compl. ¶ 30. It is true that DOCCS has relied on preliminary immunoassay screens for several years, but it is also true that of all the testing systems DOCCS used, only Defendants’ was so inadequate that it required reversal of all discipline. That is, in fact, further evidence that Defendants breached their duty of care to Plaintiff and those similarly situated.

⁷ Notably, the plaintiff in *Landon* made a similar allegation and his complaint was found sufficient to survive the motion to dismiss stage. *See Landon v. Kroll Lab. Specialists, Inc.*, 22 N.Y.3d 1, 5, 999 N.E.2d 1121, 1123 (2013).

⁸ Microgenics’s decision to relegate the issue of Defendants testifying to the reliability of the testing system to a footnote, dismissing that allegation because “Plaintiff does not allege that any Microgenics personnel testified at her disciplinary hearing,” Micro. Br. at 15 n.6, is telling. Defendants had been put on notice of deficiencies in the testing system they had provided and were maintaining, but chose to actively participate in hearings where they repeatedly

produced notoriously inaccurate results.⁹ *Id.* ¶ 46. The widespread failure of the products and services provided by Defendants led DOCCS to take the unprecedented step of reversing all discipline imposed on that basis. *Id.* These facts are *more* than enough to adequately plead breach under New York law and the cases Microgenics cites do not provide otherwise. *See Farash v. Cont'l Airlines, Inc.*, 337 F. App'x 7, 9 (2d Cir. 2009) (“recogniz[ing] that the question of whether given conduct was ‘reasonable’ under the circumstances is often reserved for the trier of fact,” but dismissing because the plaintiff failed to allege any facts at all suggesting that the airline breached its duty to protect his safety); *Patterson v. State*, 54 A.D.2d 147, 150 (1976), *aff'd*, 45 N.Y.2d 885 (1978) (only injury alleged); *Pawaroo v. Countrywide Bank*, 2010 WL 1048822, at *2 (E.D.N.Y. Mar. 18, 2010) (complaint stated only that defendant had been negligent, alleging no facts to plead any element of the cause of action).

II. PLAINTIFF’S CLASS ALLEGATIONS SHOULD NOT BE STRICKEN

Microgenics’s “motion to strike” is nothing more than a misguided preemptive opposition to class certification. It is both procedurally premature and substantively baseless. Like its motion to dismiss, Microgenics’s motion to strike is premised on a self-serving, intentionally obtuse, and inaccurate reading of the Complaint.

This action does *not* turn on whether the positive initial drug screening results produced by the Indiko Plus were false as a matter of scientific fact. Rather, the central question

testified to the lack of any such deficiencies in the system. Compl. ¶ 45. By doing so, Defendants broadly validated the testing system and allowed Plaintiff and those similarly situated to be disciplined on its basis. The fact that Defendants did not testify at Plaintiff’s individual hearing is irrelevant since their consistent and broad validation of the testing regime to DOCCS caused the breach of their duty to Plaintiff.

⁹ Microgenics complains that Plaintiff has not identified what “specific flaws” in the system caused the breach of the duty. Micro. Br. at 14. But Plaintiff does not have a heightened burden under Rule 9(b) to plead her claims with specificity, especially at this stage in the litigation, and especially where she has not yet pleaded claims for fraud or strict products liability and the technical details of the tests are uniquely within the custody and control of Defendants. *See In re LIBOR-Based Fin. Instruments Antitrust Litig.*, 962 F. Supp. 2d at 617.

in this case is whether Defendants' screening results were sufficiently reliable to support the lodging of misconduct charges and the imposition of disciplinary sanctions and harsh punishments of the sorts imposed here. This question is common and uniform to *every* putative class member without exception. *See Wal-Mart Stores, Inc. v. Dukes*, 564 U.S. 338, 359 (2011) (commonality requires only a "single common question" that unites the proposed class).

Every member of the class defined in the Complaint received a purported positive drug screen result from the testing system Defendants supplied to DOCCS. Every member of the class was charged with misconduct based on Defendants' drug testing system. Every member of the class was punished because of Defendants' products, materials, training, and testimony. Every member of the class was injured from the moment they were charged with misconduct based on a deficient and unreliable screening test because they were forced to defend charges that had no legitimate basis. As soon as each class member was issued an infraction they were immediately stripped of the hard-earned benefits, privileges, and programs they had previously obtained. Not surprisingly, the stripping of programs, desirable living arrangements, and other benefits, rights, privileges, and amenities is especially egregious precisely because it often takes years of exemplary conduct to become eligible for many such benefits, thus making these advantages and amenities invaluable and coveted by members of the proposed class, including Plaintiff. And, tragically, the injuries only worsened from there, concluding with, among other things, unjustified continued incarceration past long-awaited release dates, periods of solitary confinement, and other forms of restrictive confinement and deprivations.

A. Defendants' Attempt to Litigate Class Certification Is Premature

"Motions to strike are generally looked upon with disfavor and a motion to strike class allegations is even more disfavored because it requires a reviewing court to preemptively terminate the class aspects of litigation, solely on the basis of what is alleged in the complaint

and before plaintiffs are permitted to complete the discovery to which they would otherwise be entitled on questions relevant to class certification.” *Chen-Oster v. Goldman, Sachs & Co.*, 877 F. Supp. 2d 113, 117 (S.D.N.Y. 2012) (internal quotation marks and alterations omitted). Thus, “[g]enerally speaking,” motions to strike class allegations “are deemed procedurally premature.” *Id.*

There is a narrow exception to this general rule “if the inquiry [raised by the motion to strike] would not mirror the class certification inquiry and if resolution of the motion is clear.” *In re Initial Publ. Offering Sec. Litig.*, 2008 WL 2050781, at *2 (S.D.N.Y. May 13, 2008). For example, in several cases, courts have granted motions to strike class allegations on the basis that the claims of absent class members had not been exhausted through a mandatory administrative process. *See, e.g., Rahman v. Smith & Wollensky Rest. Grp., Inc.*, 2008 WL 161230, at *3 (S.D.N.Y. Jan. 16, 2008) (holding that this “basis for the motion to strike is distinct from [the Rule 23 certification] factors”); *Davito v. AmTrust Bank*, 743 F. Supp. 2d 114, 116 (E.D.N.Y. 2010). Notwithstanding this narrow exception, “a motion to strike class claims is considered premature if the issues raised are the same ones that would be decided in connection with determining the appropriateness of class certification under Rules 23(a) and 23(b).” *Kassman v. KPMG LLP*, 925 F. Supp. 2d 453, 464 (S.D.N.Y. 2013).

Here, Microgenics does not even pretend that the grounds for its motion to strike are distinct from the class-certification factors under Rule 23. Microgenics assert two grounds for its motion to strike.

First, it contends that the class definition is overbroad and because it allegedly includes persons who received a positive drug screen that was “legitimate” and were thus not injured. Br. at 17-18. Microgenics’s premise is false. Like Plaintiff, members of the putative

class were injured because Defendants' equipment, materials, training and conduct led to a result that was so inherently unreliable that DOCCS terminated the testing contract and reversed and expunged entirely every disciplinary result.

Second, it argues, based on the same self-serving faulty premise, that individual issues concerning "causation" overwhelm common questions. While these arguments should be rejected on the merits, they are unquestionably nothing more than run-of-the-mill litigation positions that we will see again at the proper time—in opposition to Plaintiff's motion for class certification.

Both arguments "mirror the class certification inquiry." *In re Initial Publ. Offering Sec. Litig.*, 2008 WL 2050781, at *2. Where, as here, "the issues raised in the motion to strike are the same ones that would be decided in connection with determining the appropriateness of class certification under Rules 23(a) and 23(b)," a motion to strike is improper. *Rahman*, 2008 WL 161230, at *2. Accordingly, "the better course is to deny [the] motion because the shape and form of a class action evolves only through the process of discovery." *Blagman v. Apple Inc.*, 2013 WL 2181709, at *7 (S.D.N.Y. May 20, 2013) (internal quotation marks omitted).

B. Every Member of the Putative Class Was Injured by Defendants' Negligence

The class is defined in the Complaint as all persons "who received positive drug test results generated by Indiko Plus urinalysis analyzers while in DOCCS custody in 2019 and subsequently had those positive drug tests reversed." Compl. ¶ 95. As alleged in the Complaint, and as a matter of indisputable fact, *every* person in the class was charged by Defendants and DOCCS with using banned substances. *Every* charge was based on a screening result produced by Defendants' machine using Defendants' products and operated by persons trained by Defendants. *Every* charge resulted in the imposition of severe punishment. Often months of

suffering later, *every* person so charged had those charges vacated, expunged, nullified and reversed *because* DOCCS determined that Defendants’ testing results were so unreliable that they could not support even charging an individual with misconduct. Indeed, the lack of reliability was so extreme that DOCCS cancelled the contract and sued Defendants.

Microgenics argues that “Plaintiff implausibly implies that *all* positive results derived from the Indiko Plus . . . and subsequently reversed by DOCCS were false.” Micro. Br. at 18 (emphasis in original). This is disingenuous. Plaintiff does nothing of the sort.

Instead, the Complaint alleges, directly—without implication—that the results generated by the Indiko Plus were so unreliable that they could not support the lodging of charges or the imposition of punishment. Compl. ¶ 40. Whether a different machine that actually worked in a reliable manner might have reached a similar result is irrelevant. Defendants are accountable to *every* member of the proposed class for breaching their duty to ensure the reliability of the tests they used to justify charging and punishing incarcerated persons.

C. This Is Not a Mass Tort Personal Injury Case

Microgenics is confused. It devotes nearly seven pages of its brief to arguing that individual issues predominate because “causation” cannot be established on a class-wide basis. Micro. Br. at 19-25. This is wrong as a matter of logic and law.

First, it is wrong for the same reason Microgenics’s “standing” argument fails. It fundamentally misapprehends or mischaracterizes the nature of Plaintiff’s claim. Properly understood, this case presents no troubling standing *or* causation issues because all injuries flow directly from Microgenic’s manifestly unreliable testing system. *See supra* Argument § II.B.

Second, almost every case Microgenics cites in support of its “causation” argument is a personal injury or mass tort case of the sort that presents complex issues of causation and injury that are unique to those categories of cases. *See, e.g., Amchem Prods. Inc. v.*

Windsor, 521 U.S. 591 (1997); *In re Methyl Tertiary Butyl Ether (MBTE) Prods. Liab. Litig.*, 241 F.R.D. 435 (S.D.N.Y. 2007). Those kinds of cases are, indeed, “ordinarily not appropriate for class treatment.” Micro. Br. at 24 (quoting *Amchem*). This is because determining the cause of cancer or some other physiological and sometimes latent ailment is both complex and variable from person to person in ways that are fundamentally and medically inimical to common resolution. Proving causation requires a detailed analysis of an individual’s biology, medical history, and life circumstances.

No such complexity is presented here. Plaintiffs do not allege that Defendants’ products caused a serious and/or latent medical illness, thus presenting complex causation issues. Here, the line of causation is crisp and bright. *Every* injury in this case was caused by Defendants’ unreliable tests. No charge can be brought and no punishment can be imposed based on a test result that is random and unreliable. Absent Defendants’ unreliable tests there would have been no charge and no injury. Indeed, Defendants’ testing regime has already been determined to be so woefully unreliable that DOCCS’s terminated its contract with Defendants after they reversed and expunged every charge ever brought based on a result produced by Defendants’ machines and services.

Defendants’ conduct was the functional equivalent of flipping a coin four times and charging someone with using a banned substance every time the coin landed on heads all four times. Flipping a coin four times is an inherently unreliable method of determining whether a person has ingested a banned substance. Any system that charges individuals based on such an unreliable predicate, a game of chance, is unquestionably the proximate “cause” of the injuries that flow from those charges. Like a defendant that designed a system to charge incarcerated persons with misconduct based on coin flips, Defendants here are directly responsible to each

and every member of the proposed class for the baseless charges they randomly initiated through their testing devices and services.

Finally, insofar as Microgenics argues that the individual nature of the damages suffered by members of the putative class somehow defeats predominance, it is wrong on that score as well. *See In re Nassau Cnty. Strip Search Cases*, 461 F.3d 219, 231 (2d Cir. 2006) (individualized damages do not defeat predominance under Rule 23(b)(3)).

At the proper time, after appropriate discovery and briefing, this case should be certified as a class action under Rule 23(b)(3). Defendants should be held accountable for their actions. Microgenics's motion to strike should be denied.

CONCLUSION

Plaintiff more than plausibly states a claim that Defendants Microgenics and Thermo Fisher Scientific negligently caused harm to her and others similarly situated. Plaintiff's class action allegations are more than sufficient. Defendants' motions to dismiss and to strike should be denied.

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